Listing of Claims

1. (Currently Amended) A method for treating a subject having a medical condition associated with the cardiovascular system ~~inducing vasodilation and/or increasing blood flow in a subject~~, comprising administering to the subject an effective amount of a non-acidified pharmaceutically-acceptable salt of nitrite for a sufficient period of time to induce vasodilation and/or increase blood flow in the subject thereby treating the subject, wherein the administration is by a route selected from the group consisting of intravenous injection, intramuscular injection, oral, buccal, rectal, *ex vivo*, intraocular, intraperitoneal, intravenous, intraarterial, subcutaneous, inhalation, intramuscular, and into a cardiopulmonary bypass circuit.

2. (Original) The method of claim 1, wherein the pharmaceutically-acceptable salt of nitrite reacts in the presence of hemoglobin in the subject to release nitric oxide.

3. (Currently Amended) The method of claim 1, wherein the effective amount of the pharmaceutically-acceptable salt of nitrite ~~:~~

~~——induces production in the subject of no more than about 25% methemoglobin;~~

~~——induces production in the subject of no more than about 20% methemoglobin;~~

~~——induces production in the subject of no more than about 10% methemoglobin;~~

~~——induces production in the subject of no more than about 8% methemoglobin; or~~

~~——induces production in the subject of no more than about 5% methemoglobin~~.

4. (Original) The method of claim 1, wherein the effective amount of the pharmaceutically-acceptable salt of nitrite induces production in the subject of no more than about 3% methemoglobin.

5. (Original) The method of claim 1, comprising administering sodium nitrite by injection at about 36 μmoles per minute for at least five minutes into the forearm brachial artery of the subject.

6. (Original) The method of claim 1, wherein the effective amount of the pharmaceutically-acceptable salt of nitrite is administered to a circulating concentration in the subject of about 0.6 to 240 μM.

7. (Previously Presented) The method of claim 1, wherein the pharmaceutically-acceptable salt of nitrite comprises as the cation sodium, potassium, or arginine.

8. (Original) The method of claim 7, wherein the nitrite is administered as sodium nitrite.

9. (Currently Amended) The method of claim 1, wherein the administration of the nitrite is ~~parenteral,~~ oral, ~~bucal~~buccal, rectal, *ex vivo*, or intraocular.

10. (Original) The method of claim 1, wherein the administration of the nitrite is peritoneal, intravenous, intraarterial, subcutaneous, inhaled, intramuscular, or into a cardiopulmonary bypass circuit.

11. (Previously Presented) The method of claim 1, wherein the subject is a mammal.

12. (Original) The method of claim 11, wherein the subject is a human.

13. (Previously Presented) The method of claim 1, wherein the nitrite is administered in combination with at least one additional agent.

14. (Original) The method of claim 13, wherein the additional agent is one or more selected from the list consisting of penicillin, hydroxyurea, butyrate, clotrimazole, arginine, or a phosphodiesterase inhibitor.

15. (Previously Presented) The method of claim 14, wherein the phosphodiesterase inhibitor is sildenafil.

16. (Withdrawn) The method of claim 1, wherein the subject has elevated blood pressure, and the method is a method for treating at least one vascular complication associated with the elevated blood pressure.

17. (Withdrawn) The method of claim 1, wherein the subject has a hemolytic condition, and the method is a method for treating at least one vascular complication associated with the hemolytic condition.

18. (Withdrawn) The method of claim 16, wherein the at least one vascular complication is one or more selected from the group consisting of pulmonary hypertension, systemic hypertension, peripheral vascular disease, trauma, cardiac arrest, general surgery, organ transplantation, cutaneous ulceration, acute renal failure, chronic renal failure, intravascular thrombosis, angina, an ischemia-reperfusion event, an ischemic central nervous system event, and death.

19. (Withdrawn) The method of claim 17, wherein the hemolytic condition is one or more selected from the group consisting of sickle cell anemia, thalassemia, hemoglobin C disease, hemoglobin SC disease, sickle thalassemia, hereditary spherocytosis, hereditary elliptocytosis, hereditary ovalcytosis, glucose-6-phosphate deficiency and other red blood cell enzyme deficiencies, paroxysmal nocturnal hemoglobinuria (PNH), paroxysmal cold hemoglobinuria (PCH), thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), idiopathic autoimmune hemolytic anemia, drug-induced immune hemolytic anemia, secondary immune hemolytic anemia, non-immune hemolytic anemia caused by chemical or physical agents, malaria, falciparum malaria, bartonellosis, babesiosis, clostridial infection, severe haemophilus influenzae type b infection, extensive burns, transfusion reaction, rhabdomyolysis (myoglobinemia), transfusion of aged blood, transfusion of hemoglobin, transfusion of red blood cells, cardiopulmonary bypass, coronary disease, cardiac ischemia syndrome, angina, iatrogenic hemolysis, angioplasty, myocardial ischemia, tissue ischemia, hemolysis caused by intravascular devices, and hemodialysis.

20. (Previously Presented) The method of claim 1, wherein the subject has a condition associated with decreased blood flow to a tissue, and the method is a method to increase blood flow to the tissue of the subject.

21. (Previously Presented) The method of claim 20, wherein the decreased blood flow to the tissue is caused directly or indirectly by at least one condition selected from the group consisting of: sickle cell anemia, thalassemia, hemoglobin C disease, hemoglobin SC disease, sickle thalassemia, hereditary spherocytosis, hereditary elliptocytosis, hereditary ovalcytosis, glucose-6-phosphate deficiency and other red blood cell enzyme deficiencies, paroxysmal nocturnal hemoglobinuria (PNH), paroxysmal cold hemoglobinuria (PCH), thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), idiopathic autoimmune hemolytic anemia, drug-induced immune hemolytic anemia, secondary immune hemolytic anemia, non-immune hemolytic anemia caused by chemical or physical agents, malaria, falciparum malaria, bartonellosis, babesiosis, clostridial infection, severe haemophilus influenzae type b infection, extensive burns, transfusion reaction, rhabdomyolysis (myoglobinemia), transfusion of aged blood, transfusion of hemoglobin, transfusion of red blood cells, cardiopulmonary bypass, coronary disease, cardiac ischemia syndrome, angina, iatrogenic hemolysis, angioplasty, myocardial ischemia, tissue ischemia, hemolysis caused by intravascular devices, hemodialysis, pulmonary hypertension, systemic hypertension, cutaneous ulceration, acute renal failure, chronic renal failure, intravascular thrombosis, and an ischemic central nervous system event.

22. (Previously Presented) The method of claim 21, wherein the tissue is an ischemic tissue.

23. (Previously Presented) The method of claim 20, wherein the tissue is one or more tissues selected from the group consisting of neuronal tissue, bowel tissue, intestinal tissue, limb tissue, lung tissue, central nervous tissue, or cardiac tissue.

24. (Withdrawn) The method of claim 16, wherein the elevated blood pressure comprises elevated blood pressure in the lungs.

25. (Withdrawn) The method of claim 24, wherein the subject has neonatal pulmonary hypertension.

26. (Withdrawn) The method of claim 24, wherein the subject has primary and/or secondary pulmonary hypertension.

27. (Withdrawn and Currently Amended) The method of ~~any of~~ claim 24, wherein the pharmaceutically-acceptable salt of nitrite is nebulized.

28. (Withdrawn and Currently Amended) The method of claim 27, wherein the pharmaceutically-acceptable salt of nitrite is administered to a circulating concentration in the subject of ~~:~~

~~no more than about 100 μM;~~
~~no more than about 50 μM;~~
~~no more than about 20 μM;~~
~~no more than about 16 μM; or~~
~~less than about 16 μM~~.

29. (New) The method of claim 1, wherein the effective amount of the pharmaceutically-acceptable salt of nitrite induces production in the subject of no more than about 20% methemoglobin.

30. (New) The method of claim 1, wherein the effective amount of the pharmaceutically-acceptable salt of nitrite induces production in the subject of no more than about 10% methemoglobin.

31. (New) The method of claim 1, wherein the effective amount of the pharmaceutically-acceptable salt of nitrite induces production in the subject of no more than about 8% methemoglobin.

32. (New) The method of claim 1, wherein the effective amount of the pharmaceutically-acceptable salt of nitrite induces production in the subject of no more than about 5% methemoglobin.

33. (New) The method of claim 27, wherein the pharmaceutically-acceptable salt of nitrite is administered to a circulating concentration in the subject of no more than about 50 μM.

34. (New) The method of claim 27, wherein the pharmaceutically-acceptable salt of nitrite is administered to a circulating concentration in the subject of no more than about 20 μM.

35. (New) The method of claim 27, wherein the pharmaceutically-acceptable salt of nitrite is administered to a circulating concentration in the subject of no more than about 16 μM

36. (New) The method of claim 27, wherein the pharmaceutically-acceptable salt of nitrite is administered to a circulating concentration in the subject of less than about 16 μM.

37. (New) The method of claim 36, wherein the pharmaceutically-acceptable salt of nitrite is administered to a circulating concentration in the subject of about 0.6 μM.

38. (New) The method of claim 27, wherein the pharmaceutically-acceptable salt of nitrite is administered to a circulating concentration in the subject of about 0.6 μM to about 200 μM.

39. (New) The method of claim 10, wherein the administration of nitrite is inhaled.

40. (New) The method of claim 1, wherein the route of administration of nitrite is injected.